| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/563,478 | KIMURA ET AL. | |
| | Examiner | Art Unit | |
| | Noble Jarrell | 1624 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *04 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *2-4* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2* is/are rejected.

7)☒ Claim(s) *3 and 4* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Current Status of 10 / 563478*

1. The rejection under 35 U.S.C. 102 is overcome by the amendment filed 4/4/08.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicants are not enabled for any sodium content present in the product.

> The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir., 1988). The court in Wands states, "Enablement is not precluded by the necessity for some experimentation, such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue', not 'experimentation'" (*Wands*, 8 USPQ2sd 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations" (*Wands*, 8 USPQ2d 1404). Among these factors are: (1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Consideration of the relevant factors sufficient to establish a *prima facie* case for lack of enablement is set forth herein below:

*(1) The nature of the invention and (2) the breadth of the claims:*

The claims are drawn to a process of preparing piperazine pyrophosphate from piperazine diphosphate through kneading under heat, mixed under heat, or preparation in a 4-necked flask.

*(3) The state of the prior art and (4) the predictability or unpredictability of the art:*

Prior art shows the preparation of piperazine pyrophosphate from the reaction of piperazine with sodium pyrophosphate (Berte et al., EP 126454, issued 28 November 1984, cited in IDS).

*(5) The relative skill of those in the art:*

One of ordinary skill in the art can replicate any one of examples 1-7 in the specification to produce piperazine pyrophosphate.

*(6) The amount of direction or guidance presented and (7) the presence or absence of working examples:*

The specification has provided guidance for preparation of piperazine pyrophosphate without any sodium present.

However, the specification does not provide guidance that piperazine pyrophosphate with a sodium content of 10 ppm or lower can be produced by the claimed method. In examples 1-7 of the specification, there is no indication that sodium is present in the reaction, because the product is being formed by kneading under heat, mixed under heat, or is being prepared in 4-necked flask. Table 1 (page 11) shows that the sodium content is 0 ppm in each of the examples. Comparative example 1 is not relevant because it uses a different process to produce piperazine pyrophosphate. There is no indication in the specification as to where the sodium content is coming from.

*(8) The quantity of experimentation necessary*:

Considering the state of the art as discussed by the references above, particularly with regards to claim 2 and the high unpredictability in the art as evidenced therein, and the lack of guidance provided in the specification, one of ordinary skill in the art would be burdened with undue experimentation to practice the invention commensurate in the scope of the claims.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Where is the "sodium content of 10 ppm or lower" coming from? The specification and claims give no guidance as to where this impurity will come from. Does it come from phosphoric acid in the preparation of piperazine diphosphate? In examples 1-7 of the specification, there is no indication that sodium is present in the reaction, because the product is being formed by kneading under heat, mixed under heat, or is being prepared in 4-necked flask. Table 1, page 11, shows that the sodium content is zero (0) ppm in each of the examples. Comparative example 1 is not relevant because it uses a different process to produce piperazine pyrophosphate.

***Claim Objections***

6. Claim 2 is objected to because of the following informalities: the synthetic process must be more clearly depicted. The compounds piperazine diphosphate and piperazine pyrophosphate should be shown as salts Currently, piperazine pyrophosphate is not written clearly- the OH looks like it could be a CH and is overlapping with the piperazine ring. The structures should be depicted more clearly. In addition, the formula being referred to in claim 2 is unclear because of the manner in which the claim is written. It is understood that formula I is piperazine pyrophosphate, but the way that this claim is written makes that difficult to

comprehend. Appropriate correction is required. Just as piperazine pyrophosphate is depicted in claim 2, so should the compound piperazine diphosphate, so the synthetic process is made clear to a reader of the claim.

***Allowable Subject Matter***

7. Claims 3-4 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

8. The following is a statement of reasons for the indication of allowable subject matter: Berte et al. (EP 126454, issued 28 November 1984, cited in IDS) teach the preparation of piperazine pyrophosphate from the mixing of piperazine and sodium pyrophosphate (see page 8, preparation of acid piperazine pyrophosphate). This reference does not anticipate or render obvious claim 3 or 4 because the final product is made from piperazine phosphate.

***Conclusion***

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Noble Jarrell whose telephone number is (571) 272-9077. The examiner can normally be reached on M-F 7:30 A.M - 6:00 P.M. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Noble Jarrell/
Examiner, Art Unit 1624

**/James O. Wilson/**
**Supervisory Patent Examiner, Art Unit 1624**